

## § 160.406

(1) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty—

(i) In the amount of more than \$100 for each violation; or

(ii) In excess of \$25,000 for identical violations during a calendar year (January 1 through the following December 31);

(2) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty—

(i) For a violation in which it is established that the covered entity did not know and, by exercising reasonable diligence, would not have known that the covered entity violated such provision,

(A) In the amount of less than \$100 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(ii) For a violation in which it is established that the violation was due to reasonable cause and not to willful neglect,

(A) In the amount of less than \$1,000 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than \$10,000 or more than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

## 45 CFR Subtitle A (10–12 Edition)

(A) In the amount of less than \$50,000 for each violation; or

(B) In excess of \$1,500,000 for identical violations during a calendar year (January 1 through the following December 31).

(3) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56130, Oct. 30, 2009]

### § 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity is in violation of the provision.

### § 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation, in light of the purpose of the rule violated.

(b) The circumstances, including the consequences, of the violation, including but not limited to:

(1) The time period during which the violation(s) occurred;

(2) Whether the violation caused physical harm;

(3) Whether the violation hindered or facilitated an individual's ability to obtain health care; and

(4) Whether the violation resulted in financial harm.

**Department of Health and Human Services**

**§ 160.414**

(c) The degree of culpability of the covered entity, including but not limited to:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the covered entity.

(d) Any history of prior compliance with the administrative simplification provisions, including violations, by the covered entity, including but not limited to:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the covered entity has attempted to correct previous violations;

(3) How the covered entity has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity has responded to prior complaints.

(e) The financial condition of the covered entity, including but not limited to:

(1) Whether the covered entity had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity to continue to provide, or to pay for, health care; and

(3) The size of the covered entity.

(f) Such other matters as justice may require.

**§ 160.410 Affirmative defenses.**

(a) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d-6;

(2) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the federal common law of agency, and, by exercising reasonable diligence, would not have known that the violation occurred; or

(3) The violation is—

(i) Due to reasonable cause and not willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(b) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d-6; or

(2) The covered entity establishes to the satisfaction of the Secretary that the violation is—

(i) Not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[74 FR 56131, Oct. 30, 2009]

**§ 160.412 Waiver.**

For violations due to reasonable cause and not willful neglect that are not corrected within the period described in § 160.410(a)(3)(ii) or (b)(2)(ii), as applicable, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

[74 FR 56131, Oct. 30, 2009]

**§ 160.414 Limitations.**

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.420, within 6 years from the date of the occurrence of the violation.